

Remarks

Claims 38 to 44 of this application were rejected in the Office Action mailed on February 3, 2005. Upon entry of the foregoing amendment, claims 38 to 45 are pending in the instant application.

New claim 45 is included herein. This claim has support in the original specification, for example, on pages 25 to 28. Applicants respectfully assert that no new matter is introduced by the addition of new claim 48 into the instant application.

Priority

The instant application claims priority to UK 0014046.7, filed on May 26, 2000. Although this priority claim was mistakenly not reproduced on the cover of the parent application (09/865,950), the priority is noted in the first paragraph of the issued patent (US6,667,314). The priority claim as listed in the '314 patent reads as follows:

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of priority of foreign application numbers GB 0014046.7 and GB 0015835.2, filed in Great Britain on May 26, 2000 and Jun. 27, 2000, respectively. This application also claims the benefit of priority of U.S. Provisional Application Nos. 60/214,587 and 60/219,202, filed Jun. 27, 2000 and Jul. 19, 2000, respectively.

Further, Applicants direct the examiner's attention to the published parent application, US20020013337A1, which clearly contains the relevant priority information as described above.

Accordingly, Applicants respectfully submit that the printing error on the face of the issued parent does not cause this application to be a CIP application; rather, it is a continuation application entitled to the priority as listed above.

Claim Rejections Under 35 USC § 112, 2nd ¶

Claims 40 and 44 were rejected "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the

invention.” The Examiner asserted that the term “comprises” in “modulation comprises” is open-ended and is therefore indefinite.

Without acceding to the Examiner’s assertions and purely in the interests of advancing this case to allowance, Applicants have amended the term “modulation” to “antagonizing”, as reflected in amended claims 38, 40 and 44. Applicants respectfully request withdrawal of the rejection to these claims. Further, Applicants direct the Examiner’s attention to the discussion below concerning claim rejections under 35 USC § 112, 1st ¶ and the term “modulation” in the instant application.

Claim Rejections Under 35 USC § 112, 1st ¶

Claims 40 and 44 were rejected “as failing to comply with the written description requirement. ... The instant method of treating a disorder in which the modulation of CCR5 receptors is implicated reaches out to as yet unidentified conditions/disorders in which the modulation of CCR5 receptors is implicated, a description of which is not found in the specification.”

Applicants respectfully disagree with the Examiner’s assertions. Such disorders are described at page 19, line 20 to page 20, line 12. Further, as acknowledged by the Examiner, the interaction between compounds of Formula I and CCR5 receptors is confirmed by following procedures which are clearly described in Combadiere J. et al., *Journal of Leukocyte Biology*, Volume 60 pp. 147-152 (July 1996), as referenced in the description at page 20, lines 19 to 23. A copy of this reference is attached for the Examiner’s information. The resulting data thereby clearly demonstrates the ability of the compounds of Formula I to: (i) inhibit binding of endogenous (cognate) CCR5 ligands to CCR5 (i.e., that they are modulators of CCR5); and (ii) inhibit cognate ligand-mediated signaling of CCR5 (i.e., that the compounds are CCR5 antagonists). Moreover, page 1 of the description discusses modulators, especially antagonists, of the CCR5 receptor.

However, without acceding to the Examiner’s assertions and purely in the interests of advancing this case to allowance, Applicants have amended the term “modulation” to “antagonizing”, as reflected in amended claims 38, 40 and 44. Applicants respectfully request withdrawal of the rejection to these claims.

Claim Rejections Under 35 USC § 112

Claims 40 and 44 were rejected "as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention."

Applicants respectfully disagree with the Examiner's assertions.

The Examiner has noted that no in vivo procedures are described. The biological assays described and resulting data disclose to any person skilled in the art that all the Examples are biologically potent. The description clearly states that all the Examples have an IC50 value of less than 10nM when tested in the binding assay. Indeed, the compound described in Examples 4, 6 and 7, which has an IC50 of 5nM (RANTES), is currently in Phase III clinical trials for the treatment of HIV infection. Applicants enclose an abstract from the September 2003 ICAAC conference describing the efficacy of UK-427,857 in immunotherapy clinical trials.

In further support of this view, it is noted that the compound SCH-C (Schering Corp.), which was also known to be in Phase II clinical trials for the treatment of HIV infection, has an IC50 value of 9nM (RANTES), as described in Strizki, J. et al., PNAS, Volume 98, No 22, pp12718-12723 (October 2001). A copy of this reference is also attached.

Accordingly, Applicants respectfully assert that all the rejections have been overcome and should be withdrawn. Early notice of allowance of this case is requested.

Conclusion

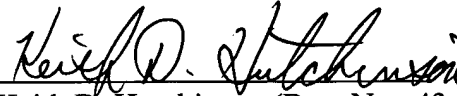
Applicants respectfully request that a timely Notice of Allowance be issued in this case.

If any fee is required for the filing of this response, including extensions of time for which Applicants hereby petition, please charge all such required fees to Deposit Account No. 500329.

Respectfully submitted,

Date: May 3, 2005

PC10925B US


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